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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/028,172 | 12/21/2001 | Yoichi Takahama | 322732000401 | 2837 |

25225 7590 11/30/2004

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| EXAMINER | |
|---|---|
| LI, BAO Q | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1648 | |

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Advisory Action | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/028,172 | TAKAHAMA ET AL. | |
| | Examiner | Art Unit | |
| | Bao Qun Li | 1648 | |

*--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

THE REPLY FILED 15 October 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☒ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See attachment of Office Action*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *None*.

   Claim(s) objected to: *None*.

   Claim(s) rejected: *31-55*.

   Claim(s) withdrawn from consideration: *None*.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)( PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Bao Qun Li

**Advisory Action**

The response to the final action filed on October 15 under 37 CFR 1.116 has been acknowledged. The request of reconsideration has been considered by the examiner but is not deemed to place the application in condition for allowance and will not be entered because:

For purpose of appeal, the status of the claims is as follows:

**Allowed claim(s): NONE.**

**Rejected claim (s): 1-55.**

**Claim(s) objected to: NONE.**

***Claim Rejections - 35 USC § 103***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 31-55 are still rejected under 35 U.S.C. 103(a) as being unpatentable over Lavanchy et al. (J. Clinical Laboratory Analysis 1996, Vol. 10, pp. 269-276), Lee et al. (Trnasfusion 1995, Vol. 35, pp. 845-849), Rosa et al. (J. Virol. Methods 1995, Vol. 219, pp. 219-232) and Wang et al. (US patent No. 5,106,726A) on the same ground as stated in the previous office Action.

3. Applicants first argue that the currently pending independent claims were all dependent claims rewritten as independent in the response and amendment filed March 4, 2004. These dependent claims had not been subject to the current rejection. Thus, Applicants respectfully submit that the outstanding rejection in the Final Office Action is a new ground of rejection that was neither necessitated by Applicants' amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 C.F.R. 91.97(c). As such, the pending claims should not be subject to a final Office Action. M.P.E.P. 706.07(a).

4. Applicant argument has been fully considered; however, it is not persuasive because the newly submitted claims 31-55 has different scope from the previous elected. claims 13-30. Therefore, the rejection is based on the new scope of the claims encomposed. The final rejection is still deem proper and than made final.

5. Regard Applicants further arguement that the reference by Lavanchy et al. is published on September 02, 1996, which is after the filling date, May 16, 1996, of priori documant of JP, 8-112442. Applicants are reminded that Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15. The rejection is based on the priority date of the parental application filed on 05/02/1997. Applicants are suggested to provide the translation of patent JP, 8-112442 to over come the rejction.

6. Applicants further argue that "Lee" reference differs from the current application in that the method disclosed by Lee is to use a strip as a solid suppot to which each HCV indivadually antigen are bounded, whereas the current application uses a mixtire of carrier particles bound with each idivadual HCV antigen. This argument is fully considered; however, it is not found persuasive because Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty, which he or she thinks the claims present in view of the state of the art disclosed by the reference cited or the objections made. Further, they do not show how the amendments avoid such references or objections. Therefore, Applicants are suggested to amend the claims with this special characteristic that overcome the rejection because both strip and carrier particle are solid support, and strip comprising bound different antigens read on same as a solid support comprising mixture of antigens because during the assay, the strip present the HCV antigens in the system as a same mixture as the claim 31 drafted since all antigen bound to the strip are present as the same time within one solid support.

7. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

8. Therefore, the rejection is proper and maintained.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li
11/26/2004

JAMES HOUSEL 11/29/04
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600